Manual: Hospital and Hospital Clinics
Chapter: Medication Management MM
Topic: Multi-dose Vials - Managing Multi-dose Vials of Injectable Medication

What are the Joint Commission's expectations for managing multi-dose vials of sterile, injectable medication ?

Any examples are for illustrative purposes only.

Definition

The CDC defines a multi-dose vial as a vial of liquid medication intended for parenteral administration (injection or infusion) that contains more than one dose of medication.

A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) tha

is meant for use in a single patient for a single case, procedure, injection.

Importance of differentiating between multi-dose and single-dose vials

Multi-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria. The preservative has no effect on viruses and does not protect against contamination when healthcare personnel fail to follow safe injection practices.

Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative. There have been multiple outbreaks resulting from healthcare personnel using single-dose or single-use vials for multiple patients.

Joint Commission Requirements

In April 2019, Joint Commission clarified that organizations should follow a hierarchical approach to compliance which includes manufacturer instructions for use (IFU). Organizations must comply with the ORIGINAL product manufacturer's IFUs. The Joint Commission Infection Control standards require organizations follow standard precautions which include medication and injection safety. Standard precautions are also

summarized in a table on the CDC Core Practices website. Organizations policies, procedures and practices are expected to incorporate these requirements.

Preparation and Use

When the product is designed for multi-dose/multi-patient use, preparation should occur in a clean, uncluttered and functionally separate area to avoid contamination. If medication was NOT prepared in a clean, uncluttered functionally separate area it should be discarded after use. Examples of acceptable practices may include:

- A patient is brought into the procedural room and the nurse accesses a multi-dose vial to administer a dose of medication to the patient receiving care and places it on the counter in case subsequent doses are needed. Any remaining medications are immediately disposed of at the end of the procedure.
- During a procedure, the physician performs hand hygiene and removed a multi-dose vial from the medication drawer of the procedure cart, after the procedure the multi-dose vial is discarded, and the top of the anesthesia cart and handles are cleaned with a disinfectant.

Expiration Dating of Multi-dose Vials

The manufacturer's expiration date refers to the date after which an unopened multi-dose vial should not be used. The beyond-use-

date refers to the date after which an opened multi-dose vial should not be used. The beyond-use-date should never exceed the manufacturer's original expiration date. Medication vials should always be discarded whenever sterility is compromised or cannot be confirmed. For example:

- If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated with the last date that the product should be used (expiration date) and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Labeling the vial with the 'date opened' does not meet the intent of this requirement
- If a multi-dose vial has not been opened or accessed (e.g., tab removed, needle-punctured), it should be discarded according to the manufacturer's expiration date which is generally printed on the label by the manufacturer.
- For expiration dates that only include the month/year, the unopened product is considered usable until the end of the month unless otherwise stated by the manufacturer.

Resources

Safe Injection Practices to Prevent Transmission of Infections to Patients

CDC: Injection Safety

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